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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,155	01/23/2001	Morris Reichlin	OMRF 158 CIP	4427

32425 7590 10/21/2005

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/768,155	REICHLIN ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-10 and 12-15* is/are pending in the application.

4a) Of the above claim(s) *1-3 and 5-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-10,12-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 8-10,12-15 are under consideration. Regarding claim 11 in the amendment filed 8/1/2005, claim 11 was cancelled in the amendment filed 1/8/2003. Applicant is required to submit a new listing of the claims with the next response that indicates that said claim has been cancelled.

2. The rejection of claims 8-10,12-14 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claims.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 9,10,12-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9 and 10 lack antecedent basis in the recitation of "anti-idiotypic antibody fragments" because claim 8 upon which said claims depend recites "anti-idiotypic Fv antibody fragments". Claim 12 lacks antecedent basis in the recitation of "anti-idiotypic antibody fragment" because claim 8 upon which said claims depend recites "anti-idiotypic Fv antibody fragments". Claims 13-15 lacks antecedent basis in the recitation of "anti-idiotypic antibody " because claim 8 upon which said claims ultimately depend recites "anti-idiotypic Fv antibody fragments".

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 8,12-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Weisbart (US Patent 6,232,444).

Weisbart teaches antiid antibodies which bind human antibodies against dsDNA (see column 2, last paragraph, columns 5 and 6, column 3). Weisbart teaches a therapeutic composition containing a Fv of said antibody (eg. a single chain antibody) in a pharmaceutical carrier (see column 3, paragraphs one and two). Weisbart teaches doses of said antibodies for treating disease (see column 3, second paragraph). The mechanisms of action recited in claim 13 and 14 would be inherent in a dosage used to treat the disease because if the anti-dsDNA antibodies were actually causing the disease than the disease would only be treated by preventing production of said antibodies. Weisbart teaches that the antibody can be a recombinant single chain Fv (see column 3, first paragraph and also see column 3, fifth paragraph wherein the VH/VL single subunit is a recombinant single chain Fv).

Regarding applicants comments, Weisbart teaches that the antibody can be a recombinant single chain Fv (see column 3, first paragraph and also see *column 3, fifth paragraph wherein the VH/VL single subunit is a recombinant single chain Fv*).

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 8-10,12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weisbart in view of Lonberg et al. (US Patent 5,789,650).

Weisbart teaches antiid antibodies which bind human antibodies against dsDNA (see column 2, last paragraph, columns 5 and 6, column 3). Weisbart teaches a therapeutic composition containing a Fv of said antibody (eg. a single chain antibody) in a pharmaceutical carrier (see column 3, paragraphs one and two). Weisbart teaches doses of said antibodies for treating disease (see column 3, second paragraph). The mechanisms of action recited in claim 13 and 14 would be present in a dosage used to treat the disease because if the anti-dsDNA antibodies were actually causing the disease than the disease would only be treated by preventing production of said antibodies. Weisbart teaches that the antibody can be a recombinant single chain Fv (see column 3, first paragraph and also see column 3, fifth paragraph wherein the VH/VL single subunit is a recombinant single chain Fv). While Weisbart discloses human antiid antibodies of the aforementioned specificity, the particular method disclosed by Weisbart to make said antibodies involves immunizing humans with an antibody that potentially causes disease wherein said immunization could not be practically accomplished for ethical/legal reasons. However, Lonberg et al. discloses that human antibodies of any specificity can be obtained by immunizing transgenic mice wherein said mice have been made transgenic with the appropriate genes that allow said mice to produce human antibodies (see column 3, last paragraph). Lonberg et al. disclose that said methods can be used to produce human antibodies wherein a human could not be ethically immunized with an antigen (for example, see column 8, penultimate paragraph). Carrier molecules are well known in the art and used for the purpose of extending the half-life of a molecule in vivo. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because while Weisbart discloses human antiid antibodies of the claimed specificity, the particular method disclosed by Weisbart to make said antibodies involves immunizing humans with an antibody that potentially

causes disease wherein said immunization could not be practically accomplished for ethical/legal reasons and Lonberg et al. discloses that human antibodies of any specificity can be obtained by immunizing transgenic mice wherein said mice have been made transgenic with the appropriate genes that allow said mice to produce human antibodies. One of ordinary skill in the art would have been motivated to do the aforementioned because Weisbart discloses human antiid antibodies of the aforementioned specificity and the potential uses of such antibodies and Lonberg et al. disclose that said methods can be used to produce human antibodies wherein a human could not be ethically immunized with an antigen.

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday to Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-2720841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RONALD B. SCHWADRON
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Ron Schwadron, Ph.D.
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Art Unit 1644